510(k) Summary Report:

Excella III-D® Spinal Deformity System

January 28, 2014

Company: Innovasis, Inc.
614 E. 3900 South
Salt Lake City, UT 84107

Contact: Marshall C. McCarty
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Trade Name: Excella® Spinal System
Excella III-D®

Common Name: Pedicle Screw Spinal System
Non-pedicle Screw Fixation System

Classification: Regulation No.: 21CFR 888.3070
Class 3 (Preamendment)
Product Code: NKB, MNI, MNH
Review Panel: Orthopedic Posterior Spine Devices Branch (PSDB)

Regulation No.: 21CFR 888.3050
Class 2
Product Code: KWP
Review Panel: Orthopedic Posterior Spine Devices Branch (PSDB)

Regulation No.: 21CFR 888.3060
Class 2
Product Code: KWQ
Review Panel: Orthopedic Posterior Spine Devices Branch (PSDB)

Applicable Standards:

- ASTM F543-07e1 Standard Specification and Test Methods for Metallic Medical Bone Screws.
- ASTM F983-86 Standard Practice for Permanent Marking of Orthopedic Implant Components
- ASTM F1717-13 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model

• ASTM F1798-97	Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
• ASTM F2193-02	Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System
• ISO 17665-1: 2006	Sterilization of Healthcare Products – Moist Heat – Part 1 Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices

Substantially Equivalent Device:

K102248	Excella II® Spinal System
K071921	Excella® Spinal System
K042143	Excella®-M Spinal System
K100788	Globus Revere® Stabilization System

Device Description: The *Excella III-D®* pedicle screws, hooks and connectors are an adjunct to the *Excella II® Spinal System.* Both the *Excella II Spinal System* and *Excella III-D Spinal Deformity System* consist of 6Al-4V titanium alloy implants meant to be used in a system. The single use devices are offered in a variety of different configurations, including screw lengths ranging from 25mm to 100mm in the following diameters, 4.0mm (new size), 4.75mm, 5.5mm, 6.5mm, 7.5mm and 8.5mm; and various hooks, rods, and connectors—and are sold non-sterile. The *Excella II* screw implants are cannulated or solid while the *Excella III-D* implants are solid only. All pedicle screws and iliac screws feature identical multi-axial joints for free motion of the screw head to allow the physician greater flexibility when placing the screws. The bone thread portion of the screws feature a self-tapping, double lead with an aggressive thread.

The *Excella II* and *Excella III-D* systems utilize identical 5.5mm titanium rods in various lengths from 35mm to 500mm (straight) or 35mm to 125mm (bent). The rods are placed in the head of the screws and the system is locked in place with titanium locking caps. The locking cap design includes a threaded locking screw attached to an alignment cap ("tulip"). Each locking cap includes a buttress thread design for axial strength and to prevent screw loosening. *Excella III-D* also features 5.5mm rods made from medical grade Cobalt-28 Chromium-6 Molybdenum, available in 500mm and 600mm lengths.

The *Excella III-D* titanium screws also have available alignment caps with extended length head (reduction head) that can be broken off after installation. Once the locking screw has been tightened in place, the added length on the alignment cap can be broken off at a tab, resulting in a final profile and assembly that is identical to a standard *Excella II* screw and locking cap assembly.

The *Excella III-D Spinal Deformity System* includes multiple sizes of hooks for use primarily in the thoracic region, and rod connectors for extension of existing constructs. The additional rod connectors (five versions) have been added to the *Excella III-D* system to allow end-to-end connection of rods. These connectors will fit both 5.5mm and 6.0mm rods. The identical locking cap is used on all *Excella II* and *Excella III-D* pedicle screws, hooks and lateral connectors. The *Excella III-D Spinal Deformity System* includes additional instrumentation to aid in de-rotation of the spine in deformity cases.

The *Excella* cross connectors come in 20, 25, 30 or 35mm fixed and various adjustable lengths from 39 to 81mm to allow for variation in perpendicular placement on two rods. Each cross connector features a clamping mechanism to grip the rods and stabilize the relation between the rods, and will work with 5.5mm and 6.0mm rods. The 20 and 25mm (shorter) sizes are new to the system.

Performance Data: (Non-clinical)—Performance testing per ASTM F1717 for Static Compression Bend, Static Torsion and Dynamic Compression Bend, Static and Dynamic Axial Compression Bend, and Axial Pullout Strength indicates that the *Excella III-D Spinal Deformity System* is capable of performing in accordance with its intended use.

Materials: The implants are machined from medical grade titanium (6AL-4V ELI) per ASTM F136-12a. Additional rods are also available from medical grade Cobalt-28 Chromium-6 Molybdenum per ASTM F1537-11.

Intended Use: Users of these products are limited to physicians trained in orthopedic surgery. Clinical locations include hospitals and surgery sites equipped to perform spinal surgery.

The *Excella III-D® Spinal Deformity System* is designed for spinal fixation procedures performed through a posterior or anterolateral approach, and is intended to assist in the temporary stabilization of spinal segments in order to provide an optimal environment for spinal fusion in the thoracolumbar region.

Indications for Use: The Innovasis *Excella III-D Spinal Deformity System*, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: Degenerative disc disease (DDD—defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

The Innovasis® *Excella III-D® Spinal Deformity System*, is also indicated for treatment of severe spondylolisthesis (Grades 3 & 4) of

the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used as a posterior non-pedicle screw fixation system, the Innovasis® *Excella III-D® Spinal Deformity System* is intended for the treatment of degenerative disc disease (DDD—defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (*i.e.*, scoliosis, kyphosis, and/or lordosis, Scheuermann's disease), fracture, pseudoarthrosis, tumor resection, and/or failed previous fusion. Overall levels of fixation are T1-sacrum/ilium.

When used as an anterolateral thoracolumbar system, the Innovasis *Excella III-D Spinal Deformity System* is intended for anterolateral screw fixation for the following indications: Degenerative disc disease (DDD—defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (*i.e.*, scoliosis, kyphosis, and/or lordosis), fracture or dislocation of the thoracolumbar spine, pseudoarthrosis, tumor resection, and/or failed previous fusion. Levels of screw fixation are T8-L5.

Basis for Substantial Equivalence:

The *Excella III-D Spinal Deformity System* has been subjected to risk analysis, engineering analysis and testing to recognized standards and has been shown to be substantially equivalent to the predicate device, K102248, *Excella II Spinal System.*

- Design configurations are substantially equivalent.
- Applied mechanical loads are substantially equivalent.
- Materials used are equivalent (6Al 4V ELI titanium) or substantially equivalent (Cobalt-28 Chromium-6 Molybdenum) and have been utilized in long term implants.
- Biocompatibility requirements have been demonstrated.
- Manufacturing and processing methods are equivalent.
- Training of Physicians and Representatives is equivalent.
- Shelf life is equivalent.

- The updated indications for use are substantially equivalent to the Globus Revere Stabilization System (K100788).
- The Cobalt-28 Chromium-6 Molybdenum utilized in the 500 and 600mm straight rods is equivalent to the CoCr rods in the Globus Revere Stabilization System (K100788).

- Mechanical testing performed to applicable ASTM standards demonstrating substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 7, 2014

Innovasis, Incorporated
Mr. Marshall C. McCarty
Director, QA/RA
614 East 3900 South
Salt Lake City, Utah 84107

Re: K140238
Trade/Device Name: Excella III-D® Spinal Deformity System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP, KWQ
Dated: April 3, 2014
Received: April 4, 2014

Dear Mr. McCarty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140238

Device Name
Excella III-D® Spinal Deformity System

Indications for Use *(Describe)*
The Innovasis Excella III-D Spinal Deformity System, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: Degenerative disc disease (DDD—defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

James P. Bertram -S
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